SUPPORTING STATEMENT
FOR
MAMMOGRAPHY FACILITIES, STANDARDS, AND LAY SUMMARIES FOR PATIENTS
21 CFR PART 900
OMB No. 0910-0309

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

The Food and Drug Administration (FDA) is requesting approval from the Office of Management and Budget (OMB) for the continuation of the information collection requirements contained in the final regulations for mammography facilities as amended. These requirements are implemented under 21 CFR Part 900 (Attachment A).

These regulations are necessary to implement the Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b) (Attachment B) as amended by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998. The MQSA requires the establishment of a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation bodies for mammography facilities, and standards for mammography equipment, personnel, and practices, including quality assurance. MQSRA extended the life of the MQSA program for four years (until 2002) and also modified some of the provisions. The most significant modification from a report and recordkeeping viewpoint under 21 CFR 900.12 (c)(2) was that mammography facilities were required to send a lay summary of each examination to the patient. The intent of these regulations is to assure safe, reliable, and accurate mammography on a nationwide level.

The regulation collects information from accreditation bodies and mammography facilities by requiring each accreditation body to submit an application for approval and to establish a quality assurance program. As a first step in becoming certified, mammography facilities must become accredited by a FDA approved accreditation body. This requires undergoing a review of their clinical images and providing the accreditation body with information showing that they meet the equipment, personnel, and quality assurance quality standards and have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer compliant mechanism. On the basis of this accreditation, facilities are then certified by FDA and must prominently display their certificate. These actions are taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

Title 21 CFR Part 900 Mammography (Attachment A), as amended, requires:

Accreditation Body Requirements:

21 CFR 900.3 - **Reporting**
Application procedure for approval as an accreditation body.

21 CFR 900.3(b)(3) - **Reporting**
Private, non-profit organizations or State agencies are required to submit three copies of an application for approval as an accreditation body.

21 CFR 900.3(c) - **Reporting**
An approved accreditation body must apply for renewal of approval or notify FDA of its plans not to apply for renewal of approval at least nine months before the expiration date of a body's approval.

21 CFR 900.3(e) - **Reporting**
An accreditation body that decides to relinquish its accreditation authority before expiration of the body's term of approval shall submit a letter of such intent to FDA at least nine months before relinquishing such authority.

21 CFR 900.3(f)(2) - **Reporting**
An accreditation body that does not apply for renewal of accreditation, is denied such approval by FDA, or relinquishes its accreditation authority shall notify all facilities accredited or seeking accreditation by the body that the body will no longer have accreditation authority.

21 CFR 900.4(c) - **Reporting**
The accreditation body shall review clinical images from each facility accredited by the body at least once every three years.

21 CFR 900.4(f) - **Reporting**
The accreditation body shall conduct onsite visits and random clinical image reviews of a sample of facilities to monitor and assess their compliance with standards established by the body for accreditation. The accreditation body shall submit annually to the FDA three copies of a summary report describing all facility assessments the body conducted under the provisions of this section for the year being reported.

21 CFR 900.4(h) - **Reporting**
The accreditation body is required to submit to FDA the information required by 42 U.S.C. 263b(d) for each facility when the facility is initially accredited and at least annually when updated. The accreditation body is required to notify FDA of applications containing information required by 42 U.S.C. 263b(c)(2) for provisional certificates and in 21 CFR 900.12(b)(2) for extension of provisional certificates. The accreditation body is required to

submit to FDA the name, identifying information, and other information for any facility for which the accreditation body denies, suspends, or revokes accreditation. The accreditation body is required to submit to FDA an annual report summarizing all serious complaints received during the previous calendar year, their resolution status, and any actions taken in response to them. The accreditation body is required to provide to FDA any other information relevant to 42 U.S.C. 263b and required by FDA about any facility accredited or undergoing accreditation by the body.

21 CFR 900.4(i)(2) - **Reporting**
At FDA's request, accreditation bodies are required to submit financial records or other material to assist FDA in assessing the reasonableness of accreditation body fees.

21 CFR 900.6(c)(1) - **Reporting**
A former accreditation body that has had its approval withdrawn may submit a new application for approval if the body can provide information to FDA to establish that the problems that were grounds for withdrawal of approval have been resolved.

21 CFR 900.3(f)(1) - **Recordkeeping**
An accreditation body that does not apply for renewal of accreditation, is denied such approval by FDA, or relinquishes its accreditation authority shall transfer facility records and other related information to a location approved by FDA.

21 CFR 900.4(g) - **Recordkeeping**
The accreditation body is required to develop and administer a written and documented system, including timeframes, for collecting and resolving serious consumer complaints that could not be resolved at a facility.

<u>General Facility Requirements:</u>

21 CFR 900.4(e) - **Reporting**
Every facility applying for accreditation is required to submit with its initial accreditation application a mammography equipment evaluation. All facilities must undergo an annual survey to assure continued compliance with accreditation standards and to provide continued oversight of facilities quality control programs as they relate to standards.

21 CFR 900.11(b)(2) - **Reporting**
New facilities beginning operation after October 1, 1994 are eligible to apply for provisional certificates.

21 CFR 900.11(b)(3) - **Reporting**
A facility may apply for a 90-day extension to a provisional certificate.

21 CFR 900.11(c) **– Reporting**

A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate revoked by FDA, may apply to have the certificate reinstated.

21 CFR 900.12(c)(2) - **Reporting**
Each facility shall maintain a system to ensure that a lay summary of his or her examination is provided to each patient and that the medical report of the examination is provided to the referring physician or, in the absence of a referring physician, to the patient. These summaries and reports are to be provided within 30 days of the examination but in cases where the assessments are "suspicious" or "highly suggestive of malignancy", they should be provided as soon as possible.

21 CFR 900.12(j)(1) - **Reporting**
If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information for review by the accreditation body or other entity designated by FDA.

21 CFR 900.12(j)(2) - **Reporting**
If FDA determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk.

21 CFR 900.15(d)(3)(ii) - **Reporting**
A facility that has been denied accreditation following appeal to the accreditation body may request reconsideration of that adverse decision.

21 CFR 900.18(c) - **Reporting**
Mammography facilities, accreditation bodies, State governments that are not accreditation bodies, and manufacturers and assemblers of equipment used for mammography may apply for approval of an alternative standard or for an amendment or extension of the alternative standard by submitting an application to FDA.

21 CFR 900.18(e) - **Reporting**
An application for amending or extending approval of an alternative standard must provide an explanation supported by data of how such an amendment or extension would assure equal or greater quality of production, processing, or interpretation of mammograms than the original standard.

21 CFR 900.11(b)(1) - **Recordkeeping**

A facility must apply to a FDA-approved accreditation body or to another entity as designated by FDA to qualify for a certificate for the lawful operation of a mammography facility.

21 CFR 900.12(c)(4) - **Recordkeeping**
Facilities are required to maintain mammography films and reports in a permanent medical record of the examinee.

21 CFR 900.12(e)(13) - **Recordkeeping**
Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials.

21 CFR 900.12(f) - **Recordkeeping**
Each facility is required to establish and maintain a mammography medical outcomes audit program. As part of that program, an interpreting physician is required to review the audit data at least once every 12 months. This individual is required to identify issues and analyze results based on this audit.

21 CFR 900.12(h) - **Recordkeeping**
Each facility is required to establish a written and documented system for collecting and documenting consumer complaints and to maintain a record of each serious complaint received by the facility for at least 3 years.

Inspection Fee Exemption

Form FDA 3422 – **Reporting**

Under the MQSA, all certified mammography facilities except governmental entities, as determined by FDA, are subject to payment of inspection fees. The information provided by this form is used by FDA to determine if the facility is operated by any Federal department, State, district, territory, possession, Federally recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof. Collection of information from this form will also allow FDA to determine if the facility provides services under the Breast and Cervical Cancer Mortality Prevention Act of 1990.

This information collection is the result of the consolidation of OMB Information Collections 0910-0309 “Mammography Facilities” and 0910-0426 “Quality Mammography Standards Lay Summaries for Patients”. Collection 0910-0426 will be retired upon OMB approval of this combined collection.

2. By Whom and for What Purpose the Information is to be Used

This information collection is being taken to assure safe, accurate, and reliable mammography on a nationwide basis. Information collected from mammography facilities has been used to ensure that the personnel, equipment, and quality systems has and continues to meet the regulations under MQSA and will be used by patients to manage their health care properly.

Certain provisions of the MQSA require that accreditation of mammography facilities by private, nonprofit organizations or State agencies be approved by FDA according to standards established by FDA. FDA has used data from the current accreditation process to ensure that the requirements of first the interim rule and now the final rule are met. The information collected for accreditation bodies of mammography facilities has been and will continue to be used by FDA to ensure that private, nonprofit organization or State agencies have met the standards established by FDA for accreditation bodies to accredit facilities that provide mammography services.

3. Consideration of Information Technology

A particularly significant use of information technology in the MQSA program to reduce the reporting and recordkeeping burden is that the accreditation bodies provide the required information to FDA almost entirely by electronic means. FDA is continuously seeking ways, through advances in information technology, to reduce burden hours. In the **Federal Register** of March 20, 1997 (62 FR 13429) (Attachment C), FDA issued a regulation that will, under certain circumstances, permit the agency to accept electronic records, electronic signatures, and handwritten signatures executed to electronic records as generally equivalent to paper records and handwritten signatures executed on paper. These regulations apply to records when submitted in electronic forms as specified in Title 21 of the Code of Federal Regulation (CFR).

An example of a particularly significant use of information technology in the MQSA program to reduce the reporting and recordkeeping burden is that the accreditation bodies provide the required information to FDA almost entirely by electronic means. Most information currently is processed through the program's electronic Mammography Program Reporting and Information System (MPRIS). Presently, accreditation bodies send information electronically through the use of web pages whereby data is updated. Inspection findings are reported electronically on the inspector's laptop and then uploaded into the system. Compliance Officers and Regional Radiological Health Representatives (RRHR) modify non-compliance information found in the inspections. Billing files are created monthly and then sent electronically to FDA's contractor who then produces the bills. The MPRIS system is essentially paperless at this point, and should currently meet Government Paperwork Elimination Act (GPEA) requirements.

Other examples of reducing burden through technology includes the FDA's permitting physician's electronic signatures on medical reports and its acceptance of electronic recordkeeping in such areas as the medical audit and patient reports. The use of electronic forms of reporting and recordkeeping submissions to FDA continues to remain voluntary at this point.

Any information generated for the patient's use may be communicated to the patient in any appropriate format.

4. Efforts to Identify Duplication and Similar Information Already Available

The MQSA was enacted to establish uniform national quality standards for all mammography facilities. Under the previous regulatory system, no national comprehensive mammography quality standards existed. The American College of Radiology (ACR) is the principal professional organization of physicians trained in radiology and medical radiation physics in the United States. In 1987, the ACR began the voluntary Mammography Accreditation Program (MAP), the purpose of which was to provide assurance of quality to patients seeking services at ACR-accredited facilities. Today, ACR is performing their accreditation program under FDA authority.

While some of the information previously included in the MAP was the same as now required by FDA under this information collection, only those facilities that had voluntarily sought accreditation previous to October 1, 1994 (less than a quarter of the total) had provided this information to the ACR. Hence, the information being collected under the MQSA has never been available for all facilities on a nationwide basis. FDA found no other information sources that were available. Because there is no similar information available to assure that mammography facilities are complying with the requirements of MQSA, the information requested under MQSA is not duplicative.

5. Impact on Small Business or Other Small Entities

FDA does not believe that the collection of information will adversely affect small businesses or other small entities. Because smaller facilities by definition have fewer employees and lower volumes of mammography examinations than large facilities, these facilities will have a lesser amount of recordkeeping and reporting burden. Thus, the amount of recordkeeping and reporting burden will be proportional to the employment at and the volume of examinations at the mammography facility. Hence, facilities of all sizes will experience an equal burden in relative terms (i.e., small facilities will not be affected any more or less than large facilities).

FDA has also attempted to minimize the information collection burden on small entities by developing a small entity compliance guide. This guide was issued under section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. Subsequently, as

additional questions arose with respect to complying with the regulations, FDA has provided further guidance in answer to these questions. Three major guidance documents have been made available, one of which concentrated specifically on recordkeeping questions, and others are in preparation. As each document becomes final, the information in it is incorporated into an electronic file called the Policy Help Guidance System. This file is available to the public on the Web Site www.fda/gov/cdrh/mammography, along with an incorporated search engine. Members of the public may consult the guidance on the Web Site or download it and the search engine to their own computer for more convenient use. This guidance, like the previously published compliance guide, is intended to help small entitles comply with the final regulations.

Further, in the interest of maintaining flexibility while improving the overall quality of mammography, FDA has provided an avenue through which an effective alternative standard may be implemented. The agency has created a mechanism for mammography facilities and accreditation bodies, State governments that are not accreditation bodies, and manufacturers and assemblers of equipment used for mammography to request permission to meet an alternative standard rather than an existing quality standard. The request must be supported by such evidence as required by the agency to render a determination that the suggested alternative is at least as effective as the agency mandated standard in helping to achieve high quality mammography.

6. Consequences of Collecting the Information Less Frequently and Technical or Legal Obstacles

Less frequent information collection may result in an unacceptable quality of mammography being provided by many facilities. Neither the accrediting bodies nor FDA would be able to assure that facilities are adequately meeting the quality standards with less frequent information collection. FDA believes that the reporting and recordkeeping frequency in the final rule is the minimum necessary to assure safe, accurate, and reliable mammography on a nationwide basis

There are no technical or legal obstacles to the collection of this information.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

This information collection is consistent with 5 CFR 1320.5(d).

8. Consultation Outside, the Agency

In accordance with 5 CFR 1320.8(d), on Monday, July 17, 2000 (65 FR 44061), a 60 day notice for public comment (Attachment D) was published in the Federal Register. No comments were received from the public.

FDA meets with its FDA's National Mammography Quality Assurance Advisory Committee (NMQAAC) twice annually. NMQAAC is made up of representatives of the mammography community, consumer groups, and government. It is charged with advising FDA's mammography program on advances in mammography technology and procedures and on appropriate quality standards for mammography facilities. The meetings are open to the public and time is allotted for public statements on issues of concern in the mammography field. The chairperson may also call upon attendees to contribute to the committee discussions.

FDA also meets several times a year with its approved accreditation bodies, which includes the American College of Radiology, to discuss issues of mutual concern. The agency has also long enjoyed a good relationship with the Conference of State Radiation Program Directors, which is the professional organization of the State agencies concerned with radiation protection. The Conference has established a standing Mammography Committee, which meets with FDA mammography staff at least once a year. In addition, it joined with FDA in forming a special Working Group to advise on the development of regulations to implement the delegation of agency authority to certify mammography facilities to individual States. The Working Group has met with FDA six times since is formation in June 1996.

Finally, in the past two years, FDA mammography staff have met several times with representatives of manufacturers working on the new applications of digital technology in mammography to resolve problems preventing the making of that technology generally available.

9. Explanation of any Payment of Gift to Respondents

No payment or gifts shall be provided to respondents under this regulation.

10. Assurance of Confidentiality Provided to Respondent

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. Mammography reports and other information submitted to FDA under 21 CFR Part 900 are releasable under the FOIA as set forth in 21 CFR Part 20.

Lay summaries issued under 21 CFR 900(c)(2) will only be available to the patient or concerned health officials.

11. Justification of Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimate of Hour Burden Including Annualized hourly Costs

The most likely respondents to this information collection will be accreditation bodies and mammography facilities seeking certification.

The total estimated annual reporting and recordkeeping burden is 3,516,183 hours. The cost of implementing requirements for certification of mammography facilities will be borne by accreditation bodies; the incremental costs which accreditation bodies will face are not expected to be significant. The cost of meeting quality standards relating to personnel, equipment, quality assurance and maintaining medical records under the interim regulations was borne by facilities, at an estimated annual cost of $22.9 million. It was estimated that the annual cost of compliance for mammography facilities would range from a high of $156.2 million in the second year of implementation to $9.5 million in the tenth year (2005). This will lead to an average comprehensive cost of $3.8 million. During the amendment of the final regulations to conform them to the provisions of MQSRA, it was estimated that the new statutory requirement to send lay summaries to all patients would increase the cost to the facilities by approximately $42.4 million in the initial year. The total cost for the initial and final regulations is $61.2 million. This cost is based upon the estimated number of summaries sent, which in turn is based on the estimated number of examinations. If mammography examinations increase in number in subsequent years, which is expected for at least the foreseeable future, the annual cost to meet this requirement will increase.

There are approximately 9800 mammography facilities performing 40 million mammograms per year. Almost all of these facilities would be considered small entities. FDA estimates the cost of providing lay summaries per mammogram would be about $1.00. The average cost per facility is estimated to be $4,080. In 90 percent of these cases, the notification to the patient can be established by a brief standardized letter to the patient. FDA estimates that preparing and sending this letter will take approximately 5 minutes. In the 10 percent of the cases in which there is a finding of “Suspicious” or “Highly suggestive of malignancy”, the facility is required to make reasonable attempts to ensure that the results are communicated to the patients as soon as possible. FDA believes that this requirement can be met by a 5 minute call from the health professional to the patient.

FDA estimates the burden of this collection of information as follows:

Table 1. --Estimated Annual Reporting Burden

CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.3	6	1	6	60	360		
900.3(b)(3)	10	1	10	60	600	$50	
900.3(c)	4	0.14	0.56	15	8.4		
900.3(e)	1	0.2	0.2	1	0.2		
900.3(f)(2)	1	0.2	0.2	200	40		
900.4(c)	834	1	834	1	834		
900.4(e)	10,000	1	10,000	8	80,000		
900.4(f)	1,000	1	1,000	14.5	14,500		
900.4(h)	6	1	750	6	4,500		
900.4(i)(2)	1	1	1	1	1		
900.6(c)(1)	1	1	1	1	1		
900.11(b)(2)	25	1	25	2	50		
900.11(b)(3)	5	1	5	.5	2.5		
900.11(c)	10,000	0.0050	50	20	1,000		$1,000
900.12(c)(2)	9,800	4,080	39,984,000	5 Minutes	3,332,000		
900.12(j)(1)	10	1	10	1	10		
900.12(j)(2)	1	1	1	50	50		
900.15(d)(3)(ii)	10,000	0.0020	20	2	40		$100
900.18(c)	10,000	0.0005	6	2	12		$60
900.18(e)	10	0.1000	1	1	1		$10
FDA Form 3422	693	1	693	.25	173		
TOTAL					3,434,183	$50	$1,170

Table 2. --Estimated Annual Recordkeeping Burden

CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating & Maintenance Costs
900.3(f)(1)	10	130	1,300	200	2,000	
900.4(g)	10,000	1	10,000	1	10,000	
900.11 (b)(1)	1,000	1	1,000	1	1,000	
900.12 (c)(4)	10,000	1	10,000	1	10,000	
900.12 (e)(13)	6,000	52	312,000	0.125	39,000	
900.12 (f)	10,000	1	10,000	1	10,000	
900.12 (h)	10,000	2	20,000	0.5	10,000	$20,000
TOTAL					82,000	$20,000

13. Estimate of the Other Total Annual Cost Burden to Respondents or Recordkeepers

A. Total Capital Cost

The total capital cost associated with these regulations is $50 (21 CFR 900.3(b)(3)). This is a one-time start up cost associated with the application for approval as an accreditation body.

B. Total Operating & Maintenance Cost

The total operating and maintenance cost associated with these requirements is: $21,170. This is the cost that facilities bear to maintain records under the initial and final mammography regulations. For example, under 21 CFR 900.12(h) (below), it is estimated that the cost to the facility to send a letter and files is about $1.00, and it is estimated that facilities perform this function approximately 20,000 times per year.

21 CFR 900.11(c)	$1,000
21 CFR 900.15(d)(3)(ii)	$100

21 CFR 900.18(c)	$60
21 CFR 900.18(e)	$10
21 CFR 900.12(h)	$20,000

These costs also cover processing mail and incoming and outgoing responses to information received and requested. This includes, but is not limited to, xeroxing, filing, etc.

14. Annualized cost to the Federal Government

FDA is currently using 60 FTE's to implement the accreditation, quality standards, and certification provisions of the MQSA. Based on a cost of $78,337 (the agency's average cost of an FTE including benefits) per position at the GS 13 grade level, the estimated yearly cost is $4,700,229. Although the number of FTE's has dropped 25 percent since the last approval of this information collection, the cost per FTE has increased about 40 per cent over the last three years. Thus, the total cost to the government since the Mammography Information Collection (0910-0309) was first approved in 1997 has increased about 8 percent.

15. Explanation for Program Changes or Adjustments

FDA had previously estimated the annual burden for reporting and recordkeeping requirements under information collection 0910-0309 to be 184,510 hours. By consolidating information collections 0910-0309 and 0910-0426, the total estimated annual reporting burden is 3,434,183 and the total estimated annual recordkeeping burden is 82,000, for a total of 3,516,183 hours. The combined collection will result in a reduction of net hourly burden by 500 hours, due to overlapping burden in each collection. Upon approval of collection 0910-0309, collection 0910-0426 will be removed from inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not Applicable

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19 of OMB Form 83-I.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no statistical methods being employed in this collection of information.

List of Attachments

Attachment A	Title 21 CFR Part 900 Mammography
Attachment B	Federal Register of March 20, 1997 (62 FR 13429)
Attachment C	Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b)
Attachment D	Federal Register of July 17, 2000 (65 FR 44061)
Attachment E	Government Entity Declaration Form FDA-3422